Remarks

Claims 1, 14, 17, 20-22, and 28 have been amended. New claims 29-32 have been added. Claims 8, 10-13, 25, and 26 were cancelled in a previous Response(s). Claims 1-7, 9, 14-24, and 27-32 are now presented for the Examiner's review and consideration. Applicants believe the amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Interview

Applicants thank the Examiner for taking the time for an interview and for courtesies extended to their representatives (Paul D. Bianco and Kfir Luzzato) during the interview of November 15, 2010. The claim amendments and remarks presented herein reflect the discussion of the interview.

Amendments to the Claims

It is noted that references to the application/specification made herein are meant only to represent examples of support for amendments and/or teachings of the application/specification and are not and are not meant to be interpreted as a comprehensive list of support. The amendments and/or referenced subject matter may also be supported in other parts of the application/specification not mentioned.

No new matter has been added by the amendments to claims 1 and 28 made herein. These claims have been amended to clarify that tattoo pigments are intracellular and puncturing releases them (the tattoo pigments) from within cells. This concept is supported in the specification as originally filed. *See* paragraphs **[0002]**; **[0003]**; and **[0032]** of the published application, U.S. Patent Application Publication 2006/0142708 A1; hereinafter "published application."

No new matter has been added by the amendment to claim 14 made herein. This claim has been amended to clarify that an aqueous solution can be injected into the pigmented section

of skin prior to puncturing (the pigmented section of skin). *See* paragraphs **[0021]** and **[0032]** of the published application.

No new matter has been added by the amendment to claim 17 made herein. This claim has been amended to clarify that the materials contained within the pad can absorb the pigments and cellular fluids in a time period of less than twenty minutes. *See* paragraph **[0029]** of the published application.

No new matter has been added by the amendment to claim 22 made herein. This claim has been amended to clarify that the pad can be removed from the punctured skin in a time period of less than twenty minutes. *See* paragraph **[0029]** of the published application.

No new matter has been added by the remainder of the amendments to claim 1 and the amendments to claims 20 and 21 made herein. These amendments have been made for consistency of language; to correct inadvertent typographical errors; to correct inadvertent errors in grammar and/or punctuation; to provide proper antecedent basis for all terms recited; and/or to coincide with amendments made to other claims.

No new matter has been added with the addition of claims 29 and 30 herein. These claims have been added to clarify that when carrying out the method of the invention the pigments can be removed within a time period of less than one hour, particularly less than twenty minutes. *See* paragraph **[0029]** of the published application.

No new matter has been added with the addition of claims 31 and 32 made herein. These claims have been added to clarify that the methods of claim 28 and 29 can further comprise injecting an aqueous solution into the pigmented section of skin prior to or during puncturing (the pigmented section of skin). *See* paragraphs **[0021]** and **[0032]** of the published application.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 22 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner asserts that the phrase "in a period of time no more than twenty minutes" is not supported by the specification.

In response, claim 22 has been amended to recite "...in a time period of less than twenty minutes." This phrase is supported explicitly in paragraph **[0029]** of the published application. Applicants note that a time period defined as less than twenty minutes can not be more than twenty minutes. Thus, claim 22 has been amended only in the interest of advancing prosecution and the amendment is not and should not be interpreted as acquiescing to the propriety of the rejection.

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph (enablement).

Rejections under 35 U.S.C. § 103(a)

Claims 1-5, 9, 14-18, 21, 23, 24, 27, and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Malodobry (U.S. Patent Application Publication 2004/0111107 A1; hereinafter "Malodobry") in view of Bogart et al. (U.S. Patent 5,271,943; hereinafter "Bogart").

Claims 6, 7, 19, and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Malodobry in view of Bogart and Garitano et al. (U.S. Patent Application Publication 2004/0158196 A1; hereinafter "Garitano").

Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Malodobry in view of Bogart and Dosch et al. (U.S. Patent 7,012,096 B2; hereinafter "Dosch").

For all reasons set forth below and those set forth in the previous Response of April 26, 2010, Applicants respectfully submit that these rejections should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches. Thus, the separate description of references presented herein is not and should not be interpreted as an attempt at arguing each reference separately.

Malodobry

Malodobry discloses a method for scarless removal of tattoos (non-natural colored pigments) from human or animal skin. *See* abstract and paragraph **[0039]**. The method includes passing one or more tools (needles), which have rough or sharp-edged surfaces, through a pigmented skin surface in a manner essentially perpendicular thereto. *See* abstract and paragraphs **[0042]** and **[0045]**. The needles enter agglomerates of color pigments and mechanically destroy them by breaking up the fragments. An abrasive agent, *i.e.* quartz or diamond dust, may be used to enhance the mechanical destruction. *See* abstract and paragraphs **[0041]-[0047]**. The smaller fragments of the agglomerates are eliminated by the natural healing process of the skin and the vitality of the cells is preserved. The pigments are shifted outwards for healthy skin to grow from beneath. *See* paragraphs **[0041]**; **[0048]**; and **[0049]**. The method may also include application of skin irritants to skin surface and/or introduction of the skin irritants into the agglomerates before, during, or after the mechanical destruction. *See* paragraph **[0050]**. The skin irritants encourage inflammation and/or provide fillers in the cells to delay wound healing. These irritants can be solid or liquid and may include table salt. *See* paragraphs **[0051]** and **[0052]** and claim 1.

Bogart

Bogart discloses therapeutic gels for promoting the healing of wounds. The gels include water, sodium chloride, and a gelling agent and have a minimum yield point of about 800 poise and a maximum apparent viscosity of about 100,000 centipoise (cps). *See* abstract and column 3, lines 10-18. The viscous properties allow the gel to conform to the interstices of a wound when applied directly thereto and to remain in the wound and not flow out when the patient moves. No dressing is required. *See* column 3, lines 36-43. The ingredients of the gels are physiologically compatible with body tissue and do not interfere with the healing process. *See* column 3, lines 60-68; column 4, lines 20-26; and column 7, line 55 to column 8, line 11. Bogart also discloses methods for treating wounds using the described gels. *See* column 1, lines 5-10; column 7, line 55 to column 8, line 11; and Example 2.

Garitano

Garitano discloses a device (and methods for using the device) for needleless administration of permanent makeup and tattoos. *See* abstract and paragraph **[0006]**. In particular, the device relates to hypodermic injectors for use in delivering pigment or other substances to targeted layers of the skin. With use of this device, one is able to avoid needlestick injuries and reduce transmission of disease. *See* abstract and paragraph **[0016]**. Material is delivered by accelerating compressed air and can be dispersed throughout a greater volume of tissue as compared to dispersion with a conventional needle. *See* paragraphs **[0016]**; **[0033]** and **[0034]**. Garitano also contemplates removal of pigment using the described device, including methods involving injection of a removal solution and suction or drainage of the solution from the skin. *See* paragraph **[0023]**.

Dosch

Dosch discloses a composition for mediating the perception of pain and methods for using the composition to treat burns and other similar injuries. *See* abstract; column 1, lines 15-20; column 4, lines 12-14, 43-50, 54-56; and claim 9. The composition includes one or more weak organic acids (acetic acid, vinegar, citric acid, and combinations thereof) blended in a pharmacologically-effective carrier, preferably a gel. *See* abstract; column 1, lines 15-20; and column 4, lines 3-5.

Instant Invention

The instant invention, as currently claimed in independent claims 1, 28, and 29, provides, *inter alia*, a method for the removal of pigments from a pigmented section of skin, for example removal of a tattoo. Generally, the method includes puncturing the skin and bandaging the skin. *See* abstract and paragraphs **[0001]** and **[0014]** of the published application. In the puncturing step, the skin is punctured in a pigmented section using a skin-puncturing device having at least

one needle. The needle punctures the pigment-containing cells which liberates the pigments and cellular fluid from within the cells. *See* paragraphs **[0002]**; **[0003]**; **[0014]**; **[0027]**; and **[0032]**. The bandaging step includes bandaging the punctured area of skin with a pad adapted to absorb the liberated pigments and cellular fluids. This pad contains one or more materials capable of accelerating migration of the liberated pigments toward an outer layer of the skin such that they can be absorbed by the pad. One or more of the materials is a salt-based granular paste. *See* paragraphs **[0014]**; **[0027]**; and **[0028]**. When bandaging, the pad is placed in direct contact with the surface of the punctured section of skin. The materials contained within the pad have direct contact with the surface of the punctured skin, but remain contained within the pad and therefore do not seep into the puncture wounds in the skin made by the needles. The pigments are removed quickly, for example, in a time period of less than an hour. *See* paragraphs **[0014]** and **[0029]**.

Argument

Applicants respectfully submit that the combination of the teachings of Malodobry and Bogart does not obviate the invention as currently claimed.

The invention provides a method of removing pigmentation, specifically tattoos, from an area of skin. The method is based upon two known facts. Firstly, in mature tattoos the pigment particles that were injected into the dermis at the time the tattoo was created are mostly found inside of cells. The cells develop around the pigment particles within a few days of the creation of the tattoo. *See* Lea et al. Int J Dermatol 26(7):453-458 1987 (abstract); attached hereto as Exhibit A and Lipper et al. *Lasers in Dermatology*, page 2508 from Chapter 267, in Fitzpatrick's Dermatology in General Medicine, sixth edition 2003; attached hereto as Exhibit B. Secondly, the small diameter of the holes created by picking the dermis with a needle close naturally within a very short period of time.

Taking these two facts into consideration, the method of the invention essentially includes two steps: Firstly, the cells containing the pigments are mechanically destroyed by means of a needle in an analogous manner to that in which the tattoo was originally created in order to liberate pigments and cellular fluids from within the cells. Secondly, after the skin has

been punctured by the needles, a specially-prepared pad is laid over the punctured area. The pad contains a material that has the property of accelerating a process of migration of the liberated pigments toward an outer layer of the skin. This material is hygroscopic and draws the aqueous mixture containing the tattoo ink pigment fragments, cellular fluid, and cellular debris to the surface of the skin where it is absorbed into the pad. The hygroscopic material is located in the pad and not placed directly on the skin surface or introduced into the holes created by the needles such that a sufficient pressure gradient will be maintained between the intracellular fluid in the dermis and the hygroscopic material to quickly draw the pigments to the skin surface. The hygroscopic force (created by the material in the pad) maximizes the amount of pigment that can be removed from the dermis in the time interval before the puncture holes close.

This method is claimed as noted above. Independent claims 1, 28, and 29 recite, *inter alia*, a method for removing pigments from a pigmented section of skin including two basic steps: puncturing a section of pigmented skin and bandaging the punctured skin with a specially-adapted pad. The puncturing (of the pigmented skin) liberates pigments from within the cells in which they (the pigments) reside. The specially-adapted pad contains material capable of accelerating migration of the liberated pigments to the surface of the skin. As a result of the accelerated migration, the pad is saturated and removed quickly, for example, within a time period of less than twenty minutes.

The rejection is based on a conclusion that use of the gel disclosed by Bogart with the method of Malodobry would constitute practice of the claimed method.

Applicants respectfully disagree. Nowhere in the prior art is such a well-aimed trauma inflicted in order to dislodge micro, intracellular foreign particles followed by hygroscopic suction to remove the dislodged particles.

The fact that one step, *i.e.* removing pigments from a pigmented section of skin, of an invention is disclosed in one reference (Malodobry) and another step, *i.e.* applying a salt-based gel to a wound, in a second reference (Bogart) does not, in and of itself, render the claimed invention an obvious combination of the two references. In other words, a simple teaching of elements/steps is insufficient to establish *prima facie* obviousness. The prior art must suggest

the desirability of the claimed invention and/or give some reason why one of ordinary skill in the art would think to combine the references.

"Obviousness can be established by combining or modifying teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so." *In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006); MPEP 2143.01 I.*

"The question under 35 U.S.C. 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time that the invention was made." *In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.*

Therefore, in order for an Examiner to properly establish a *prima facie* case of obviousness, the Examiner must not only show that all elements of the claimed invention are known or suggested in the prior art, but must also show that one of ordinary skill in the art would have some reason or motivation to put all the elements together to achieve the claimed invention.

Why would one of ordinary skill in the art decide to use Bogart's gel with Malodobry's method? These references are not reasonably combinable for a number of reasons.

Tattoo removal, in accordance with Malodobry, includes mechanically breaking up pigment agglomerates and allowing the resulting pigment fragments to be shed during natural healing of the skin; *i.e.* a scab containing the pigment fragments forms on the skin and sloughs off when new healthy cells are formed beneath it (the scab). *See* paragraphs **[0041]**; **[0048]**; and **[0049]**. Without scab formation, pigment fragments may become re-trapped in the dermis and blur, rather than completely remove, the tattoo. Thus, scab formation is required for Malodobry to achieve successful removal of a tattoo.

Bogart's composition is a therapeutic gel which promotes healing of wounds. He (Bogart) considers healing of wounds to include softening, liquefying, and removal of eschar (scab). *See* abstract; column 4, lines 60-63; and column 8, lines 42-55.

Malodobry does not disclose the need for any type of wound covering, let alone a covering that is detrimental to his desired goal (*i.e.* formation of a scab). Thus, it is highly unlikely that one of ordinary skill in the art would turn to Bogart when carrying out Malodobry's method.

Additionally, the rejection is based on a conclusion that Bogart provides a specific method for implementing Malodobry's suggestion of using a sodium chloride irritant on skin.

Applicants agree that Malodobry teaches application of skin irritants (paragraphs **[0050]-[0052]**); however the skin irritants are taught as applicable in a diluted form (paragraph **[0052]**). Thus, one can not ascertain suggestion for use of Bogart's hypertonic gel with Malodobry's method. Accordingly, there is no reasonable basis for concluding that one of ordinary skill in the art would turn to the teachings of Bogart if one happened to be looking for a way to implement Malodobry's suggested irritant application.

Furthermore, even if the cited references were combined (Malodobry and Bogart), the combination would not produce the method as currently claimed. As described above, when carrying out the claimed method, migration of liberated pigments to the surface of the skin is accelerated by application of a pad including a hygroscopic salt-based granular paste. Neither Malodobry nor Bogart can be considered as disclosing such an acceleration of pigments. Malodobry discloses removal of pigments by natural healing of the skin. Complete turnover of skin can take as long as one month. Although Bogart does disclose a hypertonic gel capable of drawing exudate from a wound (column 8, lines 1-11 and column 12, lines 40-44), the "drawing" can take hours (see Example 2 wherein the gel was changed every four-eight hours). Thus, the concept of accelerated migration of pigments can not be gleaned from the combined references (Malodobry and Bogart).

Additionally, when carrying out the claimed method, materials contained within the pad have direct contact with the surface of the punctured skin, but remain contained within the pad and therefore do not seep into the puncture wounds in the skin made by the needles. In contrast, all embodiments of Bogart's gel seep into and conform to the interstices of a wound. *See* column 3, lines 36-40. The Examiner cites portions of Bogart (column 3, lines 43-53 and column 13,

lines 4-6; page 8 of Office Action) which purportedly disclose embodiments in which the gel does not penetrate the wound. However, although the gel is applied using a gauze, the gel is disclosed as "flowing from the gauze into the wound" as in previous embodiments. *See* column 13, lines 3-8.

The addition of Garitano adds nothing to the combination of Malodobry and Bogart.

Garitano unquestionably teaches needleless administration of tattoo ink. *See* abstract and paragraphs **[0001]** and **[0006]**. Furthermore, his method was designed specifically to circumvent the disadvantages of needles. *See* paragraphs **[0002]-[0005]**. Thus, it is highly unlikely that a skilled artisan would consider the teachings of Garitano as applicable to Malodobry or any other method or device requiring needles for puncturing the skin.

Further, the addition of Dosch adds nothing to the combination of Malodobry and Bogart.

The Examiner cites column 8, lines 4-11 and asserts that Dosch discloses a gelling agent suitable for application to wounds which can be applied for a period of twenty minutes and other short periods. However, further reading of the citation indicates that the alleged twenty minute application time period is actually the time period for a herbal extraction (to prepare a herb for inclusion within the gel) and not the time the gel is applied to the skin. Dosch is unrelated to both the cited references (Malodobry and Bogart) and the claimed invention.

As evident by all of the above arguments, neither the cited references (Malodobry, Bogart, Garitano, and Dosch) nor any other prior art describe or suggest a method for removing pigments from a pigmented section of skin as is currently claimed in independent claims 1, 28, and 29.

Accordingly, Applicants respectfully submit that independent claims 1, 28, and 29 are patentable over Malodobry in view of Bogart; Malodobry in view of Bogart and Garitano; and Malodobry in view of Bogart and Dosch. As claims 2-7, 9, 14-24, and 27 depend on claim 1, claim 31 depends on claim 28, and claims 30 and 32 depend from claim 29 these dependent claims necessarily include all the elements of their base claim. Thus, Applicants respectfully submit that the dependent claims are allowable over Malodobry in view of Bogart; Malodobry in view of Bogart and Garitano; and Malodobry in view of Bogart and Dosch for at least the same

reasons.

In light of the foregoing arguments and those presented in the previous Responses, Applicants respectfully request reconsideration and withdrawal of these rejections under 35 U.S.C. §103(a).

Conclusion

In light of the foregoing amendments and remarks this application is now in condition for allowance, and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Fees for an RCE, extension of time, and extra claims are believed to be due and are being paid via credit card. However, please charge any other fee required (or credit any overpayment) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7640-X05-045).

Respectfully submitted,

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